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Stabilised lyophilised composition existing as mixture of amorphous and crystalline phases - contains non-protein pharmaceutical and synergistic combination of mannitol and alanine as stabiliser, providing stability for drug in aqueous solution

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Number of Countries: 076 Number of Patents: 013

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Priority Applications (No Type Date): FR 9513022 A 19951103

Cited Patents: Jnl.Ref; EP 394045; EP 682944; GB 2021581; JP 2096536; JP

50088215; US 4537883; WO 9323017

Patent Details:

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Abstract (Basic): WO 9717064 A

Lyophilised pharmaceutical formulation (A) consisting of amorphous and crystalline phases, comprises: (i) a non-protein active ingredient

(I); (ii) mannitol (II); and (iii) alanine (III). The weight ratio of

(II): (III) is 0.1-1.

USE - The composition is particularly useful for (I) which are not very stable in aqueous solution. (A) can be administered orally, directly, or orally or parenterally after reconstitution with water.

ADVANTAGE - (A) can be stored at 25-40 deg. C without loss of chemical or biological stability and can be reconstituted by addition of solvent. (II) and (III) have a synergistic stabilising action when used at the specified ratio; this is attributed to existence of the two-phase system.

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Title Terms: STABILISED; LYOPHILISE; COMPOSITION; EXIST; MIXTURE; AMORPHOUS

; CRYSTAL; PHASE; CONTAIN; NON; PROTEIN; PHARMACEUTICAL; SYNERGISTIC; COMBINATION; MANNITOL; ALANINE; STABILISED; STABILISED; DRUG; AQUEOUS;

SOLUTION

Derwent Class: B05; B07

International Patent Class (Main): A61K-000/00; A61K-009/14; A61K-009/19;

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